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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,396	04/12/2004	Marcus B. Jones	05986/100M724-US1	3661

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/823,396	JONES ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction

1) Claims 1-69 are under prosecution.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to an isolated nucleic acid molecule encoding a *B. anthracis* LuxS polypeptide, an expression vector and a host cell comprising the same, classified in class 536, subclass 23.7

II. Claims 11-14 and 26, drawn to an isolated *B. anthracis* LuxS polypeptide and a composition comprising the same, classified in class 530, subclass 350

III. Claims 15 and 16, drawn to an isolated antibody *B. anthracis* LuxS polypeptide and a composition comprising the same, classified in class 530, subclass 388.4

IV. Claims 17-20, 37-41 and 69, drawn to a *B. anthracis* cell in which the *luxS* gene is mutated, classified in class 435, subclass 252.31

V. Claims 21-25, drawn to a method of inhibiting growth of a *B. anthracis* cell by inhibiting the activity of a *B. anthracis* LuxS polypeptide is said cell by mutation of *luxS* gene, classified in class 935, subclass 65

VI. Claims 27-36, 67 and 68, drawn to a method for the prevention of or enhancing an immune response to *B. anthracis* infection in a subject comprising administering a vaccine comprising *B. anthracis* cells containing a mutated *luxS* gene, classified in class 424, subclass 93.2

VII. Claims 42-44, drawn to a method of preventing the growth of a *B. anthracis* cell by exposing the cell to a furanone, classified in class 435, subclass 170

VIII. Claims 45-48, 52-56 and 65-66, drawn to a method for the treatment of *B. anthracis* infection in a subject by administering a furanone, classified in class 424, subclass 246.1

IX. Claims 49-51 and 57-64, drawn to a pharmaceutical composition comprising a furanone inhibitor of a *B. anthracis* AI-2 quorum-sensing molecule or *B. anthracis* protective antigen, classified in class 514, subclass 461

3) Inventions I-IX are distinct from one another. Inventions I-IV and IX are drawn to distinct products: nucleic acid molecule; polypeptide; antibody, a mutated *B. anthracis* cell, and a furanone inhibitor. These products are distinct from one another structurally, physicochemically, functionally, immunologically and/or biologically. A polypeptide is a single chain molecule which comprises amino acid residues. A nucleic acid molecule comprises purine and pyrimidine units. Any relationship between a nucleic acid molecule and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While the polypeptide of invention II can be made by using the nucleic acid of invention I, the polypeptide can also be made without using the nucleic acid molecule of invention I , i.e., by biochemical or synthetic means. For instance, the polypeptide can be produced by chemical synthesis. An antibody is a glycoprotein which includes IgG that comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Furanone is a chemical compound. Furthermore, the nucleic acid molecule of invention I, the polypeptide of invention II, the antibody of invention III, the mutated *B. anthracis* cell of invention IV, and the furanone inhibitor of invention IX, are distinct molecules divergent with regard to their composition, structure, and function, each requiring separate and non-coextensive searches.

In the instant case, the search of the polypeptide, the nucleic acid molecule, the antibody, the mutated cell, and the furanone inhibitor are not coextensive. These inventions have a separate status in the art as shown by their different classification. In cases such as this one, where descriptive sequence information is provided, the sequence is searched in appropriate amino acid and DNA databases. There is also search burden with regard to the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest, there may be journal articles devoted solely to the polypeptide, which would not have described the nucleic acid molecule. Similarly, there may have been 'classical' genetics papers which had no knowledge of the polypeptide but described of the gene. Searching therefore is not coextensive.

4) Inventions V, VI, VII, and VIII are drawn to distinct methods, which differ from one another

in the product or reagent used therein, methods steps and parameters, method objectives, and ultimate goals used. The products used in these methods: mutated *B. anthracis* cell and a furanone, or furanone inhibitor, are divergent with regard to their structure and/or function, and classes/subclasses, each requiring separate and non-coextensive searches. Therefore, searching the above-identified inventions together would not be coextensive and thus impose a serious search burden.

5) Inventions IV and VI are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the mutated *B. anthracis* cell of invention IV can be used in a materially different process, for example, as a source of coating antigen in an *in vitro* diagnostic assay to measure specific antibodies.

Searching inventions I-IX would impose a serious search burden. These inventions have a separate status in the art as shown by their different classifications. The search for inventions V, VI, VII, and VIII would require a text search for the claimed methods in addition to a search for each product used therein. Moreover, even if each product was known, the methods, which use the product, may be novel and unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

6) The Office has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments

submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

7) In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See '*Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)', 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. 37 CFR 1.143.

9) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

11) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the telephone number is (571) 272-1600.

December, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER